DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

Feet for Life Podiatry
% Ms. Carrie Hetrick
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K141401
Trade/Device Name: Easy Out™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 20, 2015
Received: January 21, 2015

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141401

Device Name
Easy Out™

Indications for Use *(Describe)*
The Easy Out™ system is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

for

Easy Out™

1. Submission Sponsor

Feet For Life Podiatry Centers
8637 Delmar Blvd.
Saint Louis, MO 63124
United States of America
Phone: (314) 983-0303
Fax: (314) 983-2777
Contact: Dr. Michael Horwitz, CEO

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: 720.838.4113
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Carrie Hetrick, Senior Consultant, RA
Email: project.management@emergogroup.com

3. Date Prepared

February 19, 2015

4. Device Identification

Trade/Proprietary Name: Easy Out™
Common/Usual Name: Temporary Internal Fixation Device
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification Regulation: 888.3040
Classification Panel: Orthopedic
Product Code: HWC
Device Class: II

5. Legally Marketed Predicate Device(s)

Small Bone Innovations, Inc. SBI K-Wires (510(k) Number K051605, cleared August 10, 2005)

Zimmer®, Inc. Zimmer® Plates and Screws System (ZPS) – Non-Sterile, Sterile/ Non-Sterile ZPS Screws and Washers (510(k) Number K143066, cleared November 28, 2014)

Stryker® Corporation Asnis™ Micro Cannulated Screw (formally Howmedica Osteonics Corp.) (510(k) Number: K071092) 2.0mm and 3.0mm diameter implants

Stryker® Corporation, Asnis™ III Cannulated Screws (510(k) Number K024060, cleared December 20, 2002)

6. Device Description

Easy Out™ system consists of various, partially threaded solid screws designed to create lag compression used for temporary internal fixation small bones and fragments. The Easy Out™ bone screws are self-tapping, self-drilling screws with thread diameters of 2.0 mm, 2.5 mm, 3.0 mm, 3.5mm, 4.0 mm, and lengths that range from 12 mm to 60 mm. All compression screws are fabricated from medical grade titanium alloy (per ASTM F-136). Associated instrumentation is available. All compression screws are offered "non sterile".

7. Indication for Use Statement

The Easy Out™ system is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist.

8. Comparison to Predicate Devices

The Feet For Life Podiatry Centers Easy Out™ system is similar in intended use, basic shape, compatible screw diameters, materials and performance characteristics to the predicate devices. The subject devices are provided non-sterile.

9. Non-Clinical Performance Data

Performance testing and engineering analysis were conducted to characterize the performance of the Easy Out™ device. The device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices. Static and dynamic 3-point bend tests, static torsional tests and axial pull-out tests were conducted to support substantial equivalence. Static and dynamic Three Point Bend testing was conducted in accordance with ASTM F1264-03 (07), *Standard Specification and Test Method for Intramedullary Fixation Devices*. Additionally testing was conducted to characterize the torsional strength of the screw as well as axial pullout per ASTM F543-07(e1), *Standard Specification and Test Methods for Metallic Medical Bone Screws*.

Performance testing and engineering analysis were conducted to characterize the performance of the Feet for Life Easy Out™ device. The results of this testing demonstrate that Easy Out™ performs as intended and demonstrates that the device is substantially equivalence to its predicate devices.

The Easy Out™ device complies with the applicable voluntary standards for biocompatibility and sterilization.

10. Clinical Performance Data

Clinical data was not needed to support the safety and effectiveness of the subject device. Easy Out™ and its predicates are all indicated for temporary fixation. Easy Out™ does not raise any new issues of safety and effectiveness.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The Feet for Life Easy Out™ device has the same or similar intended use, indications, principles of operation, and technological characteristics as the predicate systems. Easy Out™ device is substantially equivalent to the predicate devices in terms of intended use, design, materials, and function.